Guidelines for Economic Studies for Presentation to ACIP and Working Groups

Mark L. Messonnier, M.S., Ph.D.

Lead Economist

NCIRD

Rationale

- ACIP Charter
  "deliberations…should include consideration of…efficacy, cost:benefit and risk:benefit analyses."
- Trend toward more economic studies
- Precedent
  - *BMJ* and *Vaccine*
- To ensure quality of economic data considered
  - full Committee, sub-committees, or WGs

Process Steps

- Form *ad hoc* Working Group
  - Lieu, Meltzer, Messonnier
- Write and Validate
- Implement
  - Adoption by ACIP
  - Publication

Guidelines - Materials

- Manuscript – Comparable to journal article
  - More detail
    - Methods
    - Results
  - Less detail
    - Introduction
    - Discussion
- Presentation Slides

Guidelines - Submission

- Materials to WG Chair and CDC Liaison
  - Internal and external studies, including updates
  - ≥ 8 weeks before general meeting
    - **Extraordinary** exceptions allowed
- Internal anonymous peer-review
  - NCIRD Lead Economist coordinates
    - Assigned to CDC economist
  - Reviewer consults with CDC SMEs
  - Completed review to WGC and CDCL
    - ≥ 4 weeks before general meeting
  - Review results to submitting researchers
    - Time for responses and revisions

Guidelines - Manuscript

- General
  - Author affiliations
  - Statements of potential conflicts of interest
    - *CDC and ACIP must decide details of this*

Guidelines - Manuscript

- Methods - I
  - Study Question
  - Perspective
  - Intervention Strategies
  - Time Frame and Analytic Horizon
  - Economic Model
  - Health Outcome

Guidelines - Manuscript

- Methods - II
  - Epidemiological models
  - Inputs
  - Discounting
  - Sensitivity Analyses
  - Independent Replication

Guidelines - Manuscript

- Results
  - Must answer study question
  - Must be clearly identified
  - Summary measures
    - Must be clearly presented
    - Must match perspective
  - Supplementary results may be reported

Guidelines - Manuscript

- Results
  - Tables and Graphs
    - Should stand alone
    - Should add value to manuscript
    - Supplementary tables in technical appendix
    - Standard guidelines for graphical presentation
      - e.g., Tufte

Guidelines - Manuscript

- Results
  - Sensitivity Analyses
    - Should be presented in clearly defined section
    - Include relevant tables and graphs
    - Present most influential variables

Guidelines - Manuscript

- Discussion
  - Limited
  - Limitations must be discussed
  - Relation to other relevant studies
  - How results may change
  - No policy implications
    - *unless* approved by WGC

Reference Texts Used

- *Prevention Effectiveness: A Guide to Decision Analysis and Economic Evaluation, 2d*. *Ed*. Anne Haddix, Steven Teutsch, and Phaedra Corso, editors. (New York: Oxford University Press, 2003)

- *Cost-Effectiveness in Health and Medicine.* Joanna Siegel, Louise Russell, Milton Weinstein, and Marthe Gold, editors. (New York: Oxford University Press, 1996).

- *The Visual Display of Quantitative Information*. E.R. Tufte. (Cheshire, CT: Graphics Press, 1983).

Guidelines - Slides

- Templates provided
- Total number 20-22
- Black writing on white background suggested
- Number, size, and font of words
- Standard guidelines for graphical presentation

Title of study

(should clearly represent the study question)

Authors names and affiliations

Can include logos, as desired, to identify affiliation of authors

Conflicts of interest statements

- If any author has a potential conflict of interest this must be noted, e.g.,
  - Author C: Consultant for vaccine manufacturer, *year*
- If an author or group of author have no known conflict of interests, this must be noted, e.g.,
  - Authors A, B and C: no known conflict of interests.

Methods: Study question

- Simple, complete statement of study question
- Statement of perspective(s)

Methods: Intervention(s)

- Simple statement of intervention(s) included in the study

- Statement of time frame and analytic horizon, e.g.,
  - Intervention time frame: 3 years
    Analytic horizon: outcomes counted for 10 years

- Discounting – rate used

Methods: Economic model

- Specify analytic method
  - Identify summary measure
    - This could be presented as a word equation such as
      - Cost per case averted = etc., etc.
- Simple statement of economic model

Methods: Health outcomes

- List of health outcomes measured and their perspective

Methods: Epidemiological model

If developed and used as part of research, show as a schematic diagram with suitable annotation.

Methods: Inputs

Variable	Value	Range	Source

- May have > 1 of these slides
- Inputs that should always be presented include
    - disease incidence
    - vaccine effectiveness
    - duration of immunity
    - cost

Methods: Sensitivity analyses

- Description of what sensitivity analyses were conducted
  - Type
  - Variables included
  - Ranges and sources

Results: Health Outcomes

- These could be presented in either a table or a graph.

Results: Costs

- These could be presented in either a table or a graph.

Results: Summary measure(s)

- Combine health outcomes and costs here.
- These could be presented in either a table or a graph.

Results: Additional results

- 1-2 tables and/or graphs presenting some additional results

Results: Sensitivity analyses

- 1-2 slides presenting tables or graphs showing results from sensitivity analyses

Results: Influential variables

- List/table/graph of influential variables (typically 3-5)
  - Include how they might change results.

Limitations

- List of important limitations

Relation to other studies

- If appropriate, compare results to results from other studies. Could be presented as a list or table.

Peer review comments

- 1-3 slides listing some comments from the internal peer-review.

- These slides may be presented by a CDC-based economist.